User Manual

COMBILYZER Plus

HUMAN

Cat.-No.: 17601P

CE

CONTENTS

1 INTRODUCTION 3
1.1 Methodology of Urine Testing 3
1.2 Test Strips 3
2 DESCRIPTION OF COMBILYZER PLUS 4
3 INSTALLATION 6
4 OPERATION GUIDE 8
4.1 Control Menu System 8
4.2 Setup Procedure (Menu/Setup) 8
4.2.1 Setting the Clock 8
4.2.2 Setting Serial Output Port 9
4.2.3 Setting the Language 9
4.3 Strip Setup Options (Menu/Strip) 10
4.3.1 Setting Measurement Unit 10
4.3.2 Setting the Sensitivity Attribute of the Image Processing Program 10
4.3.3 Setting Pad Sequence in the Printout 11
4.4 Service Menu Options (Menu/Service) 12
4.4.1 Code Card 12
4.4.2 Selecting Measuring Mode 13
4.5 Measurement 13
4.5.1 Setting Patient ID for Measurement 13
4.5.2 Performing Measurement 13
4.6 Memory/Data Management 15
4.6.1 Result Printout 15
4.6.2 Sending data to Host Computer 16
4.6.3 Enter Patient ID for Memory Record 16
4.6.4 Clearing Test Data from Memory 16
4.7 Printer Station 17
4.8 Serial Port 17
5 MAINTENANCE 18
6 ERROR MESSAGES AND TROUBLESHOOTING 19
7 TECHNICAL FEATURES 20
8 PACKING LIST 20
9 SYMBOLS 21
10 APPENDIX 22

This page left blank

1 INTRODUCTION

1.1 Methodology of Urine Testing

Urinalysis is one of the medical diagnosis methods frequently used by medical doctors in laboratories in order to reveal diseases.
This micro-chemistry system has been available for many years and allows qualitative and semi-quantitative analysis within one minute by simple but careful observation. The colour change occurring on each segment of the strip is compared to a colour chart to obtain the result. However, misreading or misinterpreting of results may happen, caused by individual handling habits of different users or different light conditions.

1.2 Test Strips

The COMBILYZER Plus works with **COMBINA 11S** urine test strips:
Tested parameters are as follows:

Bilirubin
Urobilinogen
Ketones
Ascorbic Acid
Glucose
Protein
Blood
pH
Nitrite
Leucocytes
Specific Gravity

2 DESCRIPTION OF COMBILYZER Plus

The **COMBILYZER Plus** is designed for urine test strip reading. The instrument includes two main functional units:

- portable, battery-operated Reader Unit for urine analysis
- bench-top, AC-powered Printer Station, which docks with the portable Reader Unit and produces printed reports.

Figure 1. Parts of COMBILYZER Plus

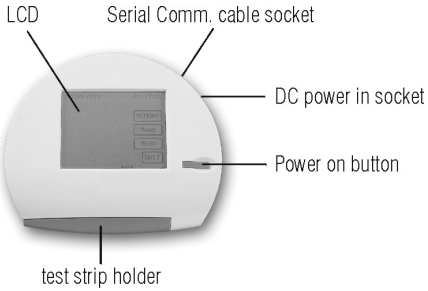


Figure 2. The Reader Unit

The Reader is menu-driven, so the operator needs to set up the Reader Unit first according to the operational conditions with the help of the function menus. After placing the moistened urine strip on the strip holder the instrument reads and evaluates the strips automatically.

The urine test strip containing chemical reagents is positioned under the reader's sensor. After the pads' colours have been evaluated, the strip should be discarded by the operator. The testing corresponds with the reaction time of the chemical reagents - about 60 seconds.

The COMBILYZER Plus works using the reflectance photometry method: inside the reader, the strip is illuminated by white light, and the light reflected from the strip is detected by a colour CCD sensor. The RGB signals are digitised using analogue-digital conversion. The digitised image is processed by a built-in program: it locates the pads and, based on the reflected light, calculates the results. The results, together with the current date, time and patient ID, are

stored and can be printed out by connecting the reader to the Printer Station.
The instrument is designed specifically for in vitro diagnostic professional use and to meet the requirements of medical professionals. The measurement capacity is up to 80 test strip evaluations per hour.

IVD

3 INSTALLATION

The COMBILYZER Plus is shipped in a cardboard box. Prior to unpacking, clear the area where the instrument is to be operated: a 30 x 50 cm size space will be needed. Please note the shipping marks on the box while handling. Open the box. Cut the tape only, leave the carton material intact. (It is recommended to keep the packaging materials)

Prepare the accessories: power adapter, rechargeable batteries and printer paper.

- Place **COMBILYZER Plus** in its operating position.
- Remove the Reader Unit from its docked position, locate its battery holder on the bottom, remove the cover-plate and load the batteries (included) as shown in figure 3. Reconnect the Reader Unit in its docked position.
- Using the standard RS232 serial cable (included) to connect the Reader Unit's serial port (see figure 2) to the computer's serial port if you intend to upload data to an external device i.e. Computer
- Connect the power adapter first to the DC socket on the reader, then to the mains.
- Switch the **COMBILYZER Plus** on by pressing the Power-On button. In a few seconds the HUMAN logo will appear on the LCD, followed by the main menu, which offers the Memory/Meas/Menu options.

Figure 3. Installation of the batteries

Note: If during power on process the user keeps any part of the LCD pressed (touched), the boot up process will be interrupted and the system information can be viewed (serial number, software version, etc.). After releasing the screen the boot up process will continue.

- Take a roll of printer paper and load it into the printer paper holder (see fig. 4) Insert the paper into the paper feeder slot and close the cover plate. The printer paper will be feed automatically to its start position. Now, the **COMBILYZER Plus** is ready to operate using the Main Menu options (see chapter 9).

Figure 4. Loading the printer paper

Note: After installation check whether the instrument is operating accurately.

4 OPERATION GUIDE

4.1 Control Menu System

The operation and functions of the **COMBILYZER Plus** can be viewed in the menu system chart (see Appendix). Each selected menu allows the user to control one of the operational or setup functions. For a detailed explanation of the submenus, please see the detailed descriptions in following chapters. Pressing the QUIT button will return to main-menu. The OK button is used to enter the edited data and quit the function.

4.2 Setup Procedure (Menu/Setup)

4.2.1 Setting the Clock

Select Menu/Setup/Clock in the menu to set date and time (see figure 5). By pressing the UP and DOWN function keys, the parameters inside the frame can be set. To go on to the next parameter press the NEXT button. By changing the SEQ. parameter the date display mode can be set from Month/Day/Year to Year/Month/Day or Day/Month/Year. When all the parameters are set, save the changes and return to the main menu by pressing OK.

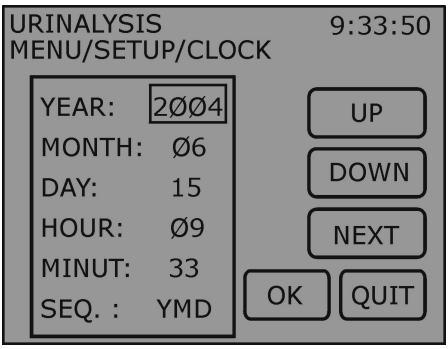


Figure 5. Clock setting

4.2.2 Setting Serial Output Port

The serial output port can be set in the Menu/Setup/Serial menu (see figure 6). If enabled, the instrument is programmed to communicate with a host computer in two ways: either PC unidirectional or network mode. Choose between the two protocols with the UP and DOWN buttons or by directly selecting the circle next to the desired protocol. In network mode, information is sent in blocks. The blocks are arranged either by sequence number (Seq. Nr.) or by patient ID. (set by the user in advance by selecting or unselecting the B1. ID.) identifies the result reports. The standard mode setting is 9600 Baud, 8 bits with 1 Stop bit and no parity. Other options can not be programmed. For more information on the serial port refer to section 4.8.

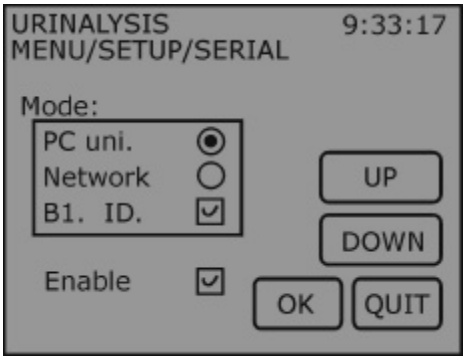


Figure 6. The serial setup menu

⚠ Note: By disabling the serial port, the printer will be disabled, too. In this case, the test results will appear only on the display.

4.2.3 Setting the Language

Select the Menu/Setup/Language menu to set the language. The instrument is programmed to communicate with the user in the following languages: English, German or Hungarian. The language can be selected with the UP and DOWN buttons or by directly marking the field next to the desired language. Store the changes and return to main menu by pressing OK.

4.3 Strip Setup Options (Menu/Strip)

4.3.1 Setting Measurement Unit

The Menu/Strip/Unit menu allows the measurement units of the test results to be selected for printed reports and the LCD.

Options are:
- Conventional
- SI
- Arbitrary
- Conventional + Arbitrary
- SI + Arbitrary

The units can be selected with the UP and DOWN buttons or by directly marking the field near the desired unit type. Store the changes and return to main menu by pressing OK.

4.3.2 Setting the Sensitivity Attribute of the Image Processing Program

Select the Menu/Strip/Sensitivity menu to adjust the sensitivity. Measurement sensitivity in the program can be adjusted on two levels in both directions (+/-) for each pad. In figure 7 the display shows the default setting for sensitivity.

The sensitivity change of each pad can be adjusted separately. Only one selected pad sensitivity can be changed at one time with the help of the UP and DOWN control buttons. When the desired sensitivity value of the previously selected test pad appears the newly selected value is set by pressing the NEXT button. After the last pad adjustment is complete, store changes and return to the main menu by pressing the OK button.

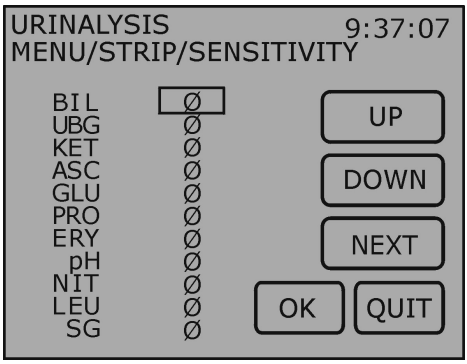


Figure 7. Setting pad

Note: When the reader has been adjusted to settings different from the standard HUMAN settings this will be indicated by asterisks in the footer of the printout.

4.3.3 Setting Pad Sequence in the Printout

Select the Menu/Strip/Padseq. submenu to change the pad sequence in the printout. In this function menu, the left column on the LCD indicates the previously set pad sequence, while the list of pads on the right shows the pad to be selected in default sequence. Figure 8 depicts the display showing the default settings of the pad sequence function menu.

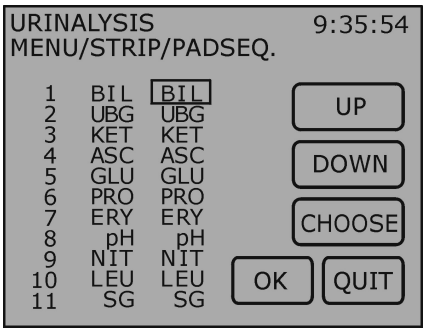


Figure 8. Changing the pad sequence

Pad names can be marked in the list on the right with the help of the UP and DOWN control buttons. When the desired pad name is marked select it by pressing CHOOSE. The selected pad name will be removed from the list on the right and appear in the first position in the list on the left. The next pad can now be chosen from the list of remaining pads on the right following the same procedure. Each succeeding pad will appear in the list on the left one position lower until there are no more pads left in the list on the right. Store the changes and return to main menu by pressing the OK button.

4.4 Service Menu Options (Menu/Service)

4.4.1 Code Card

Entering encoded test strip related information allows the **COMBILYZER Plus** to control the measurement process precisely. This coded information describes the maximum number of measurements being allowed with the given code . When opening a new vial of strips, select the Menu/Service/Calibration submenu from the menu system. Find the Calibration Card in the strip package, and enter its code . (see figure 9).

COMBILYZER Plus

0 0 0 2 7 6 0 1 3 1 4 4 4 4 4 6

Figure 9a.
Example of **COMBILYZER Plus** Calibration Card

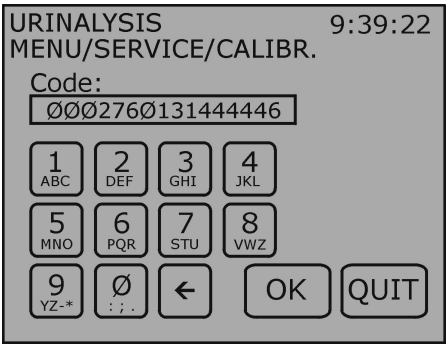


Figure 9b.
Entering the code

Note:

- Always remember to enter the code when opening a new pack of strips.

4.4.2 Selecting Measuring Mode

The COMBILYZER Plus can be operated in two different modes:

- In Timer mode, the instrument waits for the strip to incubate for 60 seconds before it reads the first pad. In this case, incubation is controlled by the instrument.
- In Fast mode, the test strip is measured directly after Start is pressed. In this case it is up to the user to time the incubation period outside the analyzer.
- In the Menu/Service/Mode submenu it is possible to toggle between Fast mode and Timer mode.

Warning! When performing serial measurements in Fast mode, allow the strips to react for approximately 55 seconds before inserting them into the **COMBILYZER Plus** and pressing Start. If the reaction (incubation) time is too short or too high false results my be obtained. Refer also to the package insert of the COMBINA 11S test strips.

4.5 Measurement

4.5.1 Setting Patient ID for Measurement

A measurement can be identified by assigning a Patient ID to it. The Patient ID can be entered before starting the corresponding measurement, or it is also possible to enter the Patient ID later in the Memory submenus (see chapter 4.6.3. for details). To assign a Patient ID for the upcoming measurement, press the Set ID button in the Meas submenu. Use the key pad displayed on LCD to type in the Patient ID and store it by pressing the OK button. The results of the measurement will be stored under the Patient ID.

4.5.2 Performing Measurement

Note: To have accurate results, never use urine that has been stored for a longer period of time or contaminated.

Use only COMBINA 11S strips with the **COMBILYZER Plus**. Refer also to the package insert of the COMBINA 11S test strips

If your **COMBILYZER Plus** has already been set up for normal operation, please, follow the instructions listed below (no 1-9), if not, follow the instructions in chapters 4.1through 4.4.

1. Prepare the urine test sample tubes.
2. Enter the Patient ID by using the Meas/SetID.
3. Press the ***Start*** button on the LCD. The strip holder tray opens automatically.
4. Dip a test strip into the urine sample for 2 sec. and remove the excess urine from strip by drawing its edge across the rim of the test or blotting it on a paper towel.
5. Place the moistened test strip with the pads facing up on the strip holder. Make sure that the leading edge of the strip is pushed against the stop.
6. Press the ***Start*** button on the LCD again. The strip holder will close automatically. The device will check if there is a strip on the strip holder and if so, the strip holder case will open half-way to allow the strip to evaporate freely. When the incubation time is over, the strip holder will close again and the measuring cycle will start.
7. From this step on, the test process is controlled automatically by the **COMBILYZER Plus**, if the Timer measuring mode has been previously selected (see chapter 4.4.2). Results are stored and will be printed out by default. In Timer measuring mode (default) a measuring cycle lasts around 60 seconds from pressing the ***Start*** button. To get the results in printed report form, the printer has to be enabled in advance (see chapter 4.8). The Reader Unit should be docked or be short distance from Printer Station.
8. To start a new measuring cycle, place a new strip on the strip holder and touch the ***Start*** button. Quit operation is accepted in such case only if there is no strip left in the strip holder, otherwise the device will continue to display a warning message until the used strip has been removed.
9. When you are finished working with the **COMBILYZER Plus** press the ***Quit*** button in main menu. After asking for confirmation of your request, the instrument will shut down automatically. If the instrument is left without input, it will shut down automatically, after 2.5 minutes if operated on batteries and after 5 minutes if connected to mains.

4.6 Memory/Data Management

4.6.1 Result Printout

Enter the Memory/Print submenu to print out records stored in the memory. A range of stored records can be selected for printing. The limits of the selected range are displayed in the top-right corner (see figure 10). They can be selected simply tapping them. The selected limit can be adjusted with the help of the UP and DOWN arrows. The lower limit can not be higher than the upper limit, therefore increasing the low limit will increase the high limit and decreasing the high limit will decrease the low limit if the value was the same. The selected range can be printed out by pressing PRINT.

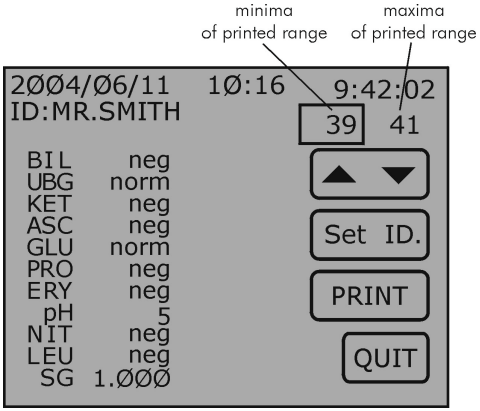


Figure 9. Selecting a memory range for printing

For example on figure 10. the low limit is 39 and 41 is the high limit of the range to be printed. Pressing the PRINT button will therefore print three records, 39-40-41.

4.6.2 Sending data to Host Computer

In the Memory/Send submenu it is possible to send records from the memory to a host computer. The selected range of measurement data (located in the selected range of memory addresses) will be sent to the receiver serial port at the pre-programmed speed. Refer to section 4.6.1. for details about setting the memory range to be sent. For setting the parameters of the serial port see section 4.2.2.

Note: Entering a new patient ID or modifying an existing one for a selected memory record is possible both in the Memory/Print and Memory/Send submenus with the Set-ID function button.

4.6.3 Enter Patient ID for Memory Record

New patient IDs can be entered or a existing IDs modified. Enter the Memory/Print or the Memory/Send submenu and choose a data record by adjusting the low limit of the memory range (see figure 10). After pressing the Set ID button, a new patient ID for the selected record can be set or an existing ID can be modified. Use the key pad to enter the patient ID and store it by pressing the OK button.

4.6.4 Clearing Test Data from Memory

All data in the memory, or only a specific record, can be deleted in the Memory/Clear submenu. The maximum number of stored records is 200. The lower and upper limits of the memory address can be set by using the UP and DOWN arrows in top-right corner of the LCD (refer section 4.6.1. for details about setting the memory range to be cleared). After setting the limits of the memory range that should be erased, press the CLEAR button. The address pointer returns to the next lower address field after execution of the memory clear function. By pressing CLR.ALL button all, existing records in the memory will be cleared.

4.7 Printer Station

The Printer Station connects the instrument to the mains voltage and also provides power for the Reader Unit if it is docked (???). Sending measurement data either to the printer or to a computer via serial port can be done the following way: first, make sure the Reader Unit is connected to the Printer Station. Data communication is executed through the infrared (IR) transmission line: either docking the Reader Unit or placing it in a direct sight line with the Printer Station. Test data of the previously selected memory range will be printed out on the built in thermo-paper printer at a speed of 2 lines per sec.

Note: The printer will operate only if it is connected to mains.

4.8 Serial Port

The **COMBILYZER Plus** serial communication protocol offers two options: either the PC Unidirectional protocol, when upon a Start signal the selected data of the test (measurement) is sent to the receiver computer, or Network protocol can be used. the communication protocol can be selected in the Menu/Setup/Serial submenu. By checking the BI. ID field it can determined whether the uploaded serial data should be identified by patient ID or by sequence ID. In this submenu all serial data flow and the printer itself can be disabled.

Note:

- Use only the serial port on the Reader Unit for uploading data to the host PC. The serial port on the Printer Station is an input only for manufacturer calibration.
- If the Enable field is unchecked, no test result will be printed out or sent through serial port. In this case test results can only be viewed on the LCD.
- The PC unidirectional protocol does not apply control sum checking.
- When sending/uploading result data to a computer, the **COMBILYZER Plus** needs to be connected to the host computer (PC) via the interface cable (included) and the serial output line needs to be enabled.

5 MAINTENANCE

Cleaning: To keep your **COMBILYZER Plus** in perfect condition never leave used strips in the strip holding tray. The **COMBILYZER Plus** checks the tray before switching off and opens it to remind the user when there is a strip left inside. The only required maintenance activity is to rinse and wipe out the strip holder with a dry cotton cloth each day before switching off the instrument.

Warning! Since urine is a fluid of human origin, biological risks cannot be ruled out. Handle used strips and urine contaminants with care!

Battery recharge: The **COMBILYZER Plus's** portable Reader Unit is powered by 3 AA size rechargeable batteries. Their fully charged capacity is sufficient for about 300 test measurements, sufficient for about a half-year of operation.
The Portable Reader Unit operates on batteries only in stand-alone mode. Docking it with the Printer Station, will recharge the batteries. The Reader Unit can also be powered by connecting the power adapter directly to its socket. If batteries are discharged, the instrument cannot be switched on. When batteries are low a „Battery low" message appears on the LCD.
In case the screen hasn't been touched for a while, the **COMBILYZER Plus** will shut down to save energy; after 2,5 minutes if operated on batteries and after 5 minutes if connected to mains.

6 ERROR MESSAGES AND TROUBLE-SHOOTING

The control program checks the operational conditions needed for proper execution of the instrument's functions. If the check ends with the indication of a malfunction, an error message will be displayed. The list of error messages, below, includes suggestions on how to eliminate problems.

Error message	Action to be done
1. Tray moving error!	check the tray opening path
2. Memory is full!	clear some memory addresses
3. Battery low!	recharge the batteries
4. Netw. comm. error!	check the serial com. synchronisation
5. Serial disabled!	enable the serial output
6. There is no strip!	load a strip into the strip holder
7. Remove the strip!	remove the strip from holder
8. Wrong calibr. code!	re-enter a valid calibration code
9. Expiry date error!	enter a valid calibration code
10. Is not meas. number!	enter a valid calibration code
11. Need calibration code!	enter a valid calibration code

Note: If a problem cannot be solved or a malfunction is experienced that is not listed above, please, contact your HUMAN distributor immediately.

7 TECHNICAL FEATURES

Technology	colour image processing
Detection	CCD image processing
Max. throughput	50 strips/hour
Memory	last 200 results
Display	touch screen LCD
Printer	57 mm thermal printer (2 lines/sec)
Size	480 x 290 x 165 mm
Weight	850 g
External power-adapter	7,5 V DC / 1.5A
Interfaces:	RS232, serial port
Op. temperature	15...30°C
Relative humidity	20-80%

8 PACKING LIST

COMBILYZER Plus instrument	1 pc
Power adapter with power cord	1 pc
Rechargeable battery	3 pcs
Strip tray	1 pc
Serial communication cable	1 pc
Printer paper	1 roll
User manual	1 pc

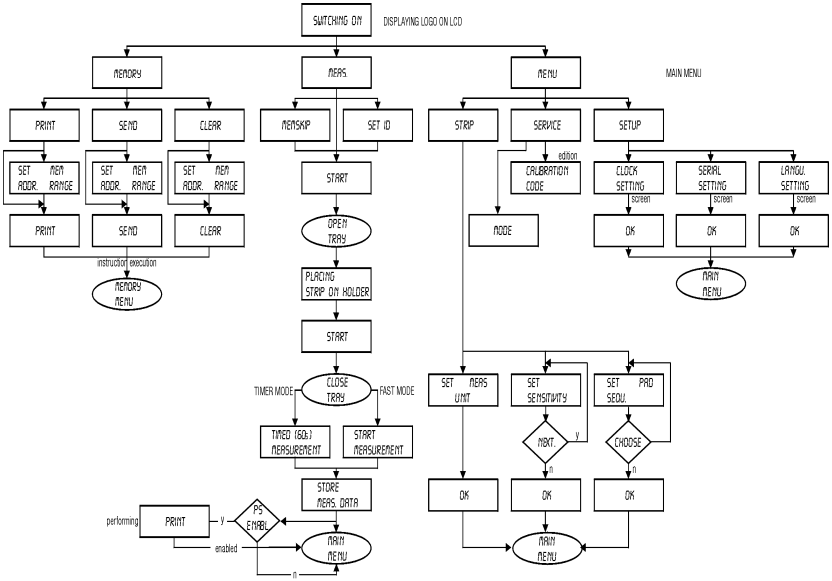
9 SYMBOLS

according to EN 980

	In vitro diagnostic medical device
	Warning
	Information inside
SN	Serial number
	Manufacturer

10APPENDIX

The Menu Structure



Human
Gesellschaft für Biochemica
und Diagnostica mbH
Max-Planck-Ring 21 • D-65205 Wiesbaden
Germany
Telefon: +49 6122 9988 0
Telefax: +49 6122 9988 100

eMail: human@human.de
Internet: http://www.human.de

02/2005-05